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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,061	09/12/2003	Charles N. Serhan	7213.13	1985

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DORSEY & WHITNEY LLP  
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MINNEAPOLIS, MN 55402-1498

EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/663,061

**Applicant(s)**

SERHAN ET AL.

**Examiner**

Hector M Reyes

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

**Status of the Claims**

Claims 1-6, 192023 and 24 have been canceled and claims 7-18, 21, 22, 25 and 26 have been withdrawn from consideration. Currently, claims 27-39 are under Examination.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inflammation, does not reasonably provide enablement for preventing inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The present determination is base in the present state in of the art: the prevention of inflammation can be treated but until now cannot be prevented. Moreover, the specification lacks to show:

- A method to determine the subjects that would certainly suffer from inflammation form the rest of the population
- A method showing the treatment that the said subjects need to undergo in order to prevent the suffering from inflammation

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- Any data showing a follow up of the said subjects already treated by a considerate amount of time in order to support the argument that the said individuals are no longer at any risk from suffering any type of inflammation

Therefore the specification fails to provide enablement for the claimed prevention of inflammation and a person skilled in the art would need to undergo exhaustive undue experimentation in order to practice the said prevention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-33 are rejected as reach through claims because:

- In claim 27, the phrase "a hydroxyl protected or unprotected monohydroxyl-docosahexaenoic acid or a pharmaceutical acceptable analogue thereof is indefinite since there is no limitation as to what possible docosahexaenoic acid may or may not satisfy the said claim limitations. What is the chemical structure of the claimed compound? What protected groups are embraced by the said phrase? Are protecting groups still to be discovered or prepared in the future also included in the said phrase?

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- In claim 28-33, the phrase "ester, amide or prodrugs" as well as the phrase "protecting group" are obscure and indefinite since it is not possible to determine what ester or amide or prodrug or protecting group- functional groups that may or may not satisfy the claims limitations. What is the structure of the said ester or protecting group, prodrug or amide moieties? How the said groups are prepared? Are future -esters, amides, protecting groups or prodrug-moieties, still to be discovered or prepared included it in the said phrase?

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by VanRollins et al, as outlined in CA 101:19194 for Journal of Biological Chemistry, (1984) 259(9), pages 5776-83.

VanRollins discloses a metabolites from rat liver microsomes after incubation of [1-14C]docosahexaenoic acid (n=3). Among the said metabolites VanRollins discloses:

- 4Z, 7Z, 10Z, 14Z, 16E, 19Z-docosahexaenoic acid 13-hydroxy, registry number 90780-53-3, thus anticipating claim 28

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- (4Z, 7Z, 10Z, 12E, 16Z, 19Z) -docosahexaenoate acid, 14-hydroxy, registry number 87042-40-8, thus anticipating claim 29
- 4Z, 7Z, 10Z, 13Z, 15E, 19Z-docosahexaenoic acid, 17-hydroxy-, registry number 90780-52-2, thus anticipating claim 30
- 4Z, 7Z, 10Z, 13Z, 17E, 19Z-docosahexaenoic acid 16-hydroxy-, registry number 90780-51-1, thus anticipating claim 33.

The particular compounds mentioned above are embraced by the generic description of the docosahexaenoic acid of claim 27, thus claim 27 is also anticipated.

Claim 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynaud et al, as outlined in CA 119:265901 for Analytical Biochemistry (1993), 214(1), pp 165-170.

Reynaud discloses the preparation and structural determination of a series of monohydroxy derivatives of docosahexaenoic acid derivatives. Among the said derivatives, Reynaud discloses:

- 4Z, 7Z, 10Z, 13Z, 16Z, 18eE- docosahexaenoic acid-20 hydroxy, having a registry number 90906-41-5, thus anticipating claim 32.

Claims 30 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Miller et al, Lipids, 24(12), pp 998-1003 (1989).

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Miller discloses 4Z, 7Z, 10Z, 13Z, 15E, 19Z)- docosahexaenoic acid, having a registry number 90780-52-2. Miller further discloses the utility of the said compound in the treatment of psoriasis and inflammatory skin disorders.

**CONCLUSION**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hector M. Reyes, whose telephone number is (571) 272-0691. The Examiner can normally be reached Monday through Friday from 9:30 to 5:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Ms. Cecilia Tsang can be reached at (571) 272-0562.

Hector M. Reyes, PhD JD  
Reg # P-54,846  
AU 1625  
September 27, 2004

*R. Desai*  
9/27/04